

REMARKS

The amendments to the claims do not add new matter. The amendments to the claims are consistent with the disclosure in the specification and in the priority application USSN 08/920,630, filed 08/27/97, now abandoned. In particular, support for the bone being “allograft” bone is found in priority application USSN 08/920,630 at page 2, lines 21-22 (“the implant is derived from allograft or autograft cortical bone sources. . .”). Support for the assembled graft being chemically “treated” so as to be “suitable for implantation into humans” is found in priority application USSN 08/920,630 at page 3, lines 23-25 (“so that the finished product may be treated by standard techniques known in the art (alcohol, peroxide, or like treatments), prior to storage and shipment to physicians for use in implantation procedures.”); and at page 18, lines 28-29 (“Following implantation, the recipient (whether human or animal) is monitored for implant stability and success in fusion.”).

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Objection /Rejection

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis).

Claims 26, 27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis).

Each of these four (4) bases for rejection are addressed in Sections I-IV, respectively, which follow.

I. Obviousness Type Double Patenting

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. The attorney for the common assignee of both pending applications is cofiling with this response an appropriate terminal disclaimer. Accordingly, this basis for provisional rejection has been rendered moot.

II. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)

A Ellis does not teach or suggest a “graft” as the term is understood in the art

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ellis anticipates the claim language where the bone pieces or bone portions of the **same** patient are grafted back **onto the bones they were separated from** to form a graft. . . .” [Official Action at page 3, citing Ellis at the figures, the abstract, and column 5, lines 12-56; emphasis added in bold.] The word “graft” never appears in Ellis and it is for a good reason. As a person skilled in the art, Ellis knew that he was not “grafting” when he re-attached a fragment of bone to the **same** site from which it fractured. In the bolded language above, the Patent Office acknowledges that Ellis discloses binding the bone back to the location that it was “**separated from,**” i.e., the **same** location. Also in FIGs 2a-2d and FIGs. 3 and 4 of Ellis, Ellis discloses binding a “bone fragment” to the **same** “bone mass” from which it separated. [See the discussion in Ellis at col. 5, lines 40-42.] As support for the Patent Office’s position that the separated “bone fragment” of Ellis is a “graft,” the Patent Office cites to Stedman’s Medical Dictionary, 23rd Edition at page 599 for the definition of “graft” as “anything **inserted** into something else so as to become an integral part of the latter.” [Official Action at page 4; emphasis added in bold.] **Applicants request a copy of this cited page so that they can see the full definition in its full context.** However, the definition upon which the Patent Office relies misses the fine part of the definition which requires that the “anything” come from a “**different site or source.**” As support for the Applicants’ position, the Applicants cite to the following three medical dictionaries, including Stedman’s (24th Edition), the successor of the Edition relied

upon by the Patent Office, which did include the specific definition of the term “**bone graft**” which is the exact term in Applicants’ claims:

graft - a tissue or an organ taken from a site or a person and inserted into a **new site or person**, performed to repair a defect in structure.

[Exhibit A of response to the Official Action of 03/24/05: Mosbey’s Medical, Nursing and Allied Health Dictionary, The C.V. Mosbey Co., St Louis, 1990, Eds. Glanze, et al., at page 531 ; emphasis added in bold.]

* * *

grafting - The implantation of skin or other tissue, **from a different site or source**, to replace damaged tissue.

[Exhibit B of response to the Official Action of 03/24/05: Dorland’s Illustrated Medical Dictionary, W.B. Saunders & Co., 24th Edition, Philadelphia, 1965, at page 629; emphasis added in bold.]

* * *

bone graft - bone transplanted from a **donor site** to a **recipient site**.

[Exhibit C of response to the Official Action of 03/24/05: Stedman’s Medical Dictionary, 24th Edition, Williams & Wilkins, Baltimore, 1982, at page 604, emphasis added in bold.]

Thus, the art as a whole, including the Stedman’s dictionary, such as relied upon by the Patent Office, recognizes that a “graft,” and particularly a “**bone graft**” is tissue that comes from a “**different site or source**.” Further, the Patent Office’s reliance upon a general definition of a “graft” taken out of context, when a specific definition of a “**bone graft**” is likely present is legal error. *See e.g., In re Lunsford*, 148 USPQ 721, 724 (CCPA 1966) (reversing the Board’s conclusion of obviousness where the board relied on the “general” teachings of the prior art while ignoring the “specific” teachings, stating: “Thus, the Examiner erred in *ignoring* the specific teachings of the primary references **without references** containing **specific teachings demonstrating that the specific teachings in Biel I and III could be ignored.**”); *In re Fournet*, 148 USPQ 740, 742 (CCPA 1966) (“We regard the use of the prior art teachings under 35 U.S.C. § 103 as a two-way street available to both parties. We

are required to evaluate the references *as a whole* regardless of the party offering the references. In Lunsford, we refuse to ignore **specific teachings which we believed would be given greater weight than general teachings by one of ordinary skill in the art.** [emphasis added in bold]. If Applicants did the same, it would be grounds for inequitable conduct. **Hence the Applicants renew their request for a copy of cited page 599 from Stedman's Medical Dictionary, 23rd Edition.**

In addition, the definition of "graft" relied upon by the Patent Office recites as follows: "anything **inserted** into something else so as to become an integral part of the latter." [Official Action at page 4; emphasis added in bold.] Consistent with the definition above, the word "inserted" means that something came from the outside. However, the bone fragment that is being re-attached to the patient never came from the outside or somewhere else, so as to be inserted. Rather, it came from **inside** the patient to be affixed to the **same** location from where it originated.

In response to the Applicants' evidence and arguments above, the Patent Office contends that "there is no special definition for this term [i.e., "graft"] in the specification." [Official Action at page 5.] The Applicants disagree. The Applicants' specification uses the term "autograft" in its ordinary sense to mean donor tissue from the same patient to be treated, but wherein the tissue comes from a "**first**" donor site that differs from a "**second**" recipient site:

The goal is best achieved by using **autograft bone from a first site for implantation into a second site.** However, use of **autograft** material is attended to by the significant disadvantage that a **second site of morbidity must be created** to harvest autograft for implantation into a first diseased or injured site.

[Specification at page 1, line 29 to page 2, line 1; emphasis added in bold.]

Thus, the Applicant's specification use the term "graft" and "bone graft" as indicative of something from another site, consistent with the dictionary definitions above. More importantly, the art recognizes that "allograft" bone is non-living bone that has been processed to remove

Further, the art has long recognized, as evidenced by issued U.S. patents in the present art, which patents are consistent with Applicants' dictionary definitions, that from the past through the present, a graft is a "**replacement**" item as opposed to the repair of an existing item:

The **term "graft"**, as used herein, refers to a natural or synthetic implantable **substitute** for various kinds of tissue.

[Exhibit D: U.S. Pat. 5,916,216, filed 11/04/96 at col. 1, lines 59-61; emphasis added in bold.]

* * *

Where the **term "graft"** is used, **those skilled in the art will recognize** that this implies that a portion of a physiological passage is **replaced** or interconnected to other such passages by means of the implant.

[Exhibit E: U.S. Pat. 6,290,718, filed 02/02/98, at col. 6, lines 9-12; emphasis added in bold.]

Thus, the relevant art, like the dictionary definitions, considers a graft to be a "**replacement**" or a "**substitute**" (which means that it comes from somewhere else) and not a "repair" of the existing parts. By analogy, if you took your car to the dealer and they **replaced** your engine, it would be different than if they **repaired** your engine.

Accordingly, when Ellis discloses binding a fractured "fragment of bone" back to its original bone mass, the fragment is not a "graft" because the broken piece of bone is from the **same** fracture site, rather than a **different** site. . It is not from a "**different site or source**" or from a "**donor site**," that is intended for a second recipient "**site**." For all these reasons, claims 26-28, 30-31 and 33-34 are not anticipated by U.S. Pat. 5,147,367 (Ellis) under 35 U.S.C. § 102(b).

B. Ellis does not teach or suggest the use of "allograft bone"

Although the above arguments of record alone are sufficient to overcome the Examiner's rejection, the Applicants have amended independent claims 26-28 and 31-34 to facilitate the prosecution on the merits. In particular, the Patent Office correctly points out

that Ellis discloses “bone pieces or bone portions of the **same** patient are grafted back **onto the bones they were separated from** to form a graft. . . .” [Official Action at page 3.] Assuming for the sake of argument that these bone portions are “grafts,” one skilled in the art recognizes that this bone from the **same** patient is called an “autograft.” More importantly, in Ellis, this bone which from the same patient and the same site as the fracture is inherently “**living** bone” that is filled with living cells.

In contrast, the Applicants have amended each of independent claims 26-28 and 31-34 to reflect that the bone of the claims is “allograft ” bone. One skilled in the art recognizes that “allograft” bone, which by definition comes from a **different member** of the same species, are **non-living bone** that has been chemically and physically processed to remove fat, viruses (such as HIV), foreign protein, bone marrow and cells which might induce an immune response or rejection of the graft in the recipient, thereby making it suitable for implanting in a human patient. [See Exhibit F: U.S. Pat. 5,556,379 (Wolfinbarger), “Process for Cleaning Large Bone Grafts and Bone Grafts Produced Thereby,” filed 02/27/95, issued 09/17/96, at col. 1, line 25 to col. 3, line 11.] Likewise, U.S. Pat 5,513,662, entitled “Preparation of bone for transplantation,” which issued TO Morse on 05/07/96, discloses as the Background, the need in allograft bone of decontaminating to remove pathogens and cleaning to remove antigens (immunogens), to render the allograft bone suitable for implanting into a human patient:

The present invention relates to methods of processing bone for transplantation. More particularly, the invention is directed to the provision of decontaminated bone, transplant of which **minimizes substantially exposure of the transplant recipient to contaminating pathogens or immunogenic material.**

REPORTED DEVELOPMENTS

The procurement and processing of **human bone for transplantation** is a complicated task which requires the coordinated efforts of several groups including the donor's family, the hospital staff, the local procurement group, the blood specimen processing laboratory, the **bone processing** laboratory, the transplant patient, and the transplant team.

A **prime consideration** is minimization of the risk of **transferring potentially harmful diseases to tissue recipients.** In fact,

provision of **bone tissue safe for transplantation** provides a very special challenge as **immunogenic material and also microorganisms and viruses can be found deep within the internal matrix of bone samples.**

In this regard, blood samples may be analyzed at the processing laboratory for a variety of known infectious agents including, for example,

Human immunodeficiency virus (HIV-1)

Human immunodeficiency virus (HIV-2)

Human T cell lymphotropic virus (HTLV-1)

Hepatitis B

Hepatitis C

Cytomegalic virus (CMV)

Treponema pallidum (syphilis).

With respect to the serious clinical consequences resulting from the transplanting of contaminated bone see, for example, Kakaiya et al., "Tissue transplant-transmitted infections," Transfusion 31 (3), 1277-284, 1991; Shutkin, "Homologous-serum hepatitis following use of refrigerated bone-bank bones, report of a case", Journal of Bone and Joint Surgery, 16-A(1), 160-162, 1954. Transmission of human immunodeficiency virus (HIV) via bone as well as bone marrow has also been reported. "Transmission of HIV through bone transplantation case report and public health recommendations" Novbid. Mortal. Weekly Rep., 37, 597-599, 1988; Furlini et al., "Antibody response to human immunodeficiency virus after infected bone marrow transplant", Eur. J. Clin. Microbiol. Infect. Dis. 7(5) 554-665, 1988. HIV has been cultured from fresh as well as refrigerated bone and freeze-dried bone. Buck et al. "Human immunodeficiency virus cultured from bone. Implications for transplantation", Clin. Ortho., 251, 249-253, 1990. Additionally, protection of technicians at the bone processing laboratory is of great concern because of the serious potential for transmission of HIV and hepatitis B.

A further and **very important consideration** with respect to the design of bone processing methodologies is **avoiding or minimizing immune response (including transplant rejection)**

in the recipient patient to donor macromolecules remaining in the transplanted bone, such as collagens, and cell surface antigens of the major histocompatibility complex or other glycoproteins. See, for example, Friedlander and Horowitz, *Orthopedics*, 15(10), 1171-1175 (1992), and Mankin, et al., *Id.*, at 1147-1154.

Accordingly, there is a **great need for bone processing methods that decrease the risk of recipient immunological response or disease transmission associated with the use of, and preparation and procurement of, transplantable bone**. In this regard it is also important to recognize that even if state of the art donor screening methodology is used, recent infections in a particular donor may not be detected, thereby underscoring the importance of improved cleaning and decontaminating treatments that offer prophylactic protection against potential, or as yet undetected, infectious agents.

The combination of donor screening and antibiotic treatments traditionally employed during bone processing reduces, but do not limit to an acceptable level, the risk of transmission of known viral contaminants and a variety of bacteria. See, for example, Scarborough, N. L., *Orthopedics*, 15(10), 1161-1167 (1992), and Malinin, T. I., "Acquisition and Banking of Bone Allografts", in *Bone Grafts and Bone Substitutes*, Habal and Reddi, eds., Chapter 19, pp. 206-225, W. B. Saunders Company, Philadelphia, Pa. (1992). As aforementioned, currently-available methods offer no prophylactic protection from viruses, select bacteria, and fungi which are common flora in humans or in a hospital environment. Although the sensitivity and specificity of screening tests for such pathogens are high, screening tests are not foolproof, and false negatives may result from, for example, low antibody levels (e.g., recent infection or immunodeficiency) or even technician error. Furthermore, screening tests may be useful only to identify known infectious agents. Additionally, the aforementioned traditionally-used antibiotic antibacterial cocktails currently in use do not readily kill all types of bacteria. For example, a commonly used polymyxin/bacitracin solution (50,000 units bacitracin/500,000 units polymyxin B) does not inactivate *Proteus* species. Furthermore, traditional antibiotic cocktails have no significant effect on viruses or fungi.

There are also significant limitations on the extent to which decontaminating agents have been used successfully to penetrate and to decontaminate matrix of bone. See Prolo and Oklund, "Sterilization of Bone by Chemicals", in *Osteochondral Allografts-Biology, Banking and Clinical Applications*, Friedlaender et al.,

eds., Chapter 22, pp. 233-238, Little, Brown and Company, Boston, Mass. (1983). **Bone matrix contains potentially removable materials, for example, marrow, cells and lipid that impede access of decontaminating agents deep into bone matrix where, as aforementioned, infectious agents or immunogenic macromolecules may be present.**

Certain of the difficulties encountered in extracting removable materials from the bone matrix are described, but not resolved, according to Great Britain Patent Specification 964,545, published in 1964.

The '545 Specification describes a procedure for using a **fat solvent** (for example, a chloroform/methanol mixture) for cleaning of bone. Substantial periods of time are involved that are inconsistent with preferred bone banking procedures, such as to rapidly match a donor bone piece of appropriate size for a recipient. An additional disadvantage stated to be inherent in this methodology is that it appears to be restricted to a particular series of steps that must be performed in a particular order. If this is not done, **immunogenic donor proteins are stated to remain in the bone owing to in situ denaturation thereof caused by the fat solvent.**

These and other difficulties associated with the **provision of decontaminated bone suitable for transplantation** are resolved according to the practice of the invention.

[Exhibit G: U.S. Pat. 5,513,662, at col. 1, line 12 to col. 3, line 5; emphasis added in bold]

Consistent with the well-know understanding in the art that “allograft” bone must be cleaned and non-living, the Applicants’ specification discloses a process for tissue “cleaning” and “decontamination”:

In developing the various embodiments of the present invention, one technical issue of merit is the need to develop a process whereby donor tissue, whether hard or soft tissue, **allograft or xenograft** tissue, may be treated in such a fashion as **to eliminate the possibility of cross contamination between tissue segments obtained from different sources.** While it is possible to practice the present invention to advantage using tissue obtained from a single screened donor, the real economies of scale and commercially viable application of the present technology is best

realized by implementation of an efficient and reliable **tissue decontamination process**. Ideally, the process is one which permits multiple segments of soft or hard tissue to be treated simultaneously so that a stock of materials for assemblage of implants according to the present invention is facilitated. Accordingly, on preferred method for treatment of tissue, disclosed in PCT publication WO 00/29037, the disclosure of which is hereby incorporated herein by reference as if fully set forth herein (and priority of the US Patent filings which gave rise to this application is hereby claimed for that purpose). Accordingly, in this aspect of the invention, a process is claimed whereby an **assembled allograft or xenograft tissue implant** is prepared by **treating** the tissue in a closed container in which **different cleaning solutions** are contacted with the implant segments, either before or after assembly and machining into the final implant form, either in the presence or absence of sonication, with rapid oscillation of pressure in the closed container, **to achieve deep cleaning** and interpenetration of cleaning solvents into the interstices of porous implants or tissues. Solutions including, but not limited to **detergent solutions, peroxide solutions** and the like are used in such procedure, and **terminal sterilization with gamma irradiation**, gaseous sterilants known in the art or other terminal sterilization procedures known in the art are employed to ensure safe implantation of the assembled implants according to this invention.

[Specification at page 8, lines 6-29; emphasis added in bold.]

Thus, when the applicants claim as an element “allograft bone” to produce an assembled graft that is suitable for implanting in a human patient,” the allograft bone was inherently cleaned and decontaminated so as to be “**non-living**” and free of foreign proteins, bacteria and viruses. For these reasons, the allograft bone employed in the Applicants’ invention is structurally different than the **living** bone that is being repaired in Ellis

By analogy, one cannot claim a DNA molecule because it would read on a product as found in nature. However, one can claim the “isolated and purified DNA molecule.” Likewise, in the present case, any allograft bone that is “suitable for implantation into a human patient” has been cleaned and isolated and is inherently non-living (like a natural sponge found in the grocery store as opposed to a sponge picked fresh from the ocean seabed). For these reasons, claims 26-28 and 31-34 and their dependents (claims 29-30) are

neither anticipated by Ellis, nor would they have been obvious over Ellis as of their earliest claimed priority date (August 27, 1997).

C. Ellis does not teach or suggest an “assembled implant suitable for implantation into a human patient”

Separately, each of independent claims 26-28 and 31-34 have been amended to recite that the “assembled” bone graft is “suitable for implantation into a human patient.” See the Specification at page 8, lines 19-29. As a result, the claimed bone graft of the Applicants’ invention must be in an “assembled” form outside the body, so as to be suitable (in assembled form) for implantation into the body. In contrast Ellis fails to teach any bone graft (or implant) that is assembled outside the body. To the extent that Ellis can be said to teach anything that is assembled, the actual assembly of any bone occurs in the body of which living bone and living bone fragments in the human body are an integral part of the assembly. Ellis teaches a surgical repair technique (using pins or screws to resecure a living bone fragment back to its original location). Ellis never teaches or suggests an “assembled bone graft” having a separate existence in “assembled” form outside the patient so as to be “suitable for implantation into a human patient.” For this separate reason, claims 26-28 and 31-34 and their dependents (claims 29-30) are neither anticipated by Ellis, nor would they have been obvious over Ellis as of their earliest claimed priority date (August 27, 1997).

III. 35 U.S.C. § 103(a) over U.S. Pat. 5,147,367 (Ellis)

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ellis discloses using ‘any number of pins or screws’ to secure the bone portions together but not the use of ‘four’ pins as claimed.” [Official Action at page 4.] The Patent Office then contends that “the use of ‘four’ pins would have been considered *prima facie* obvious to an ordinary artisan. [Official Action at page 4.] The Applicants respectfully submit that the cited reference fails to make a *prima facie* case of obviousness against the presently claimed invention.

As an initial matter, claims 61 and 62 are ultimately dependent upon claims 31 and 33, respectively. As discussed in Section II *supra*, independent claims 31 and 32 include

as an element bone portions of “allograft” bone, which are is processed and non-living in order to be “suitable for implantation into humans.” In contrast in Ellis, the fragment of bone that is re-attached to the site from which it fractured is “living” bone. One skilled in the art recognizes that the “living” autograft bone of Ellis is structurally different than the dead and highly processed “allograft” bone of the Applicants’ invention. Thus, even if Ellis could be construed as suggesting the use of 4 pins, Ellis would not have rendered obvious the Applicants’ invention as a whole because Ellis never taught or suggested the use of dead and processed tissue, and particularly not “allograft.”

Separately, Ellis never teaches or suggests a graft that is “assembled” outside the body so as to be “suitable for implantation into the body.” Rather in Ellis, the only “assembled bone” exists exclusively in the body because the main bone mass to which a fragment is re-attached is part of the living human body.

For any one of these reasons, claims 61-62 would not have been obvious over the disclosure in Ellis.

IV. 35 U.S.C. § 103(a) over U.S. Pat. 5,716,358 (Ochoa) in view of Ellis

Claims 26-27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ochoa discloses bone portions or pieces **grafted back onto the bones they were separated from . . .**” [Official Action at page 4, citing Ochoa at Figures 4 and 5, and column 6, line 57 to col. 8, line 47; emphasis added in bold.] In the bolded language above, the Patent Office acknowledges that Ochoa discloses binding the bone back to its **original** location (*i.e.*, the location that it was “**separated from**”). In the same sentence, the Patent Office admits that Ochoa “**fails to clearly disclose the use of a plurality of pins as now claimed.**” [Official Action at page 4; emphasis added in bold.] To make up for this admitted deficiency, the Patent Office cites to Ellis for allegedly disclosing that “it was well known to use a plurality of pins to attach bone pieces together.” [Official Action at page 4; emphasis added in bold.] The Applicants respectfully submit that the cited combination fails to make a *prima facie* case of obviousness against the presently claimed invention.

In particular, each of independent claims 26-27 and 31-34 have been amended to recite that the bone portions therein are “allograft” bone. Because the claimed grafts are also “suitable for implantation in humans,” the “allograft” bone of the claims is **non-living** and has been processed to remove fat, proteins, and cells, the latter two which would be recognized as foreign and rejected by the graft recipient. Unless “allograft” bone is non-living and has been processed to remove foreign antigens (i.e., proteins and cells) it would not be suitable for use in humans. In marked contrast, both Ochoa and Ellis, as acknowledged by the Patent Office, teach how to repair a patient’s own bone inside his body. In particular, Ochoa and Ellis teach how to re-attach a fractured fragment of **living** bone back to its original **living** bone mass. Neither Ochoa nor Ellis discloses or suggest the use of “allograft” bone. For this reason alone, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

Separately, each of the Applicants’ claims is directed to an “assembled bone graft” that is “suitable for implantation into a human patient.” Thus, the “assembled” bone graft must exist in “assembled” form **outside** the body of a human patient to be “suitable for implanting into a human patient.” In contrast, in both Ochoa and Ellis, the “assembled” bone species only exists in “assembled” form **inside** the body of the human patient because it is assembled *in vivo*. Hence, at no time does Ochoa or Ellis teach or suggest an “assembled” bone graft (that exists in assembled form outside the body) so as to be “suitable for implantation into a human patient.” For this reason also, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

SUMMARY

Claims 26-34 and 61-62 are pending and subject to rejection.

In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-34 under 35 U.S.C. § 102 (b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. In view of the evidence, arguments and/or amendments herein, the rejection of claims 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot.

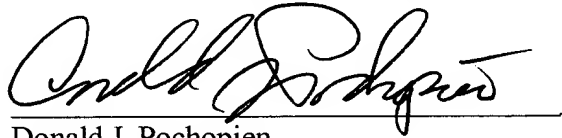
In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-27, 31-34 and 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot.

Claims 26-34 and 61-62 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

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By:

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